

Claims

WHAT IS CLAIMED IS:

1. - 53. (canceled)
54. (new) A lyophilisate comprising as an active ingredient flupirtine in base form or as a physiologically tolerated salt and suitable for producing a pharmaceutical composition for parenteral administration.
55. (new) The lyophilisate according to claim 54, comprising at least 100 mg of flupirtine.
56. (new) The lyophilisate according to claim 54, wherein the physiologically tolerated salt is an acid addition salt of flupirtine.
57. (new) The lyophilisate according to claim 56, wherein the acid of the acid addition salt is selected from the group consisting of gluconic acid, formic acid, acetic acid, propionic acid, succinic acid, glycolic acid, lactic acid, malic acid, tartaric acid, citric acid, ascorbic acid, maleic acid, fumaric acid, hydroxymaleic acid, pyruvic acid, phenylacetic acid, benzoic acid, p-aminosalicylic acid, embonic acid, methanesulphonic acid, ethanesulphonic acid, hydroxyethanesulphonic acid, ethylenesulphonic acid, halobenzenesulphonic acid, toluenesulphonic acid, naphthalenesulphonic acid, sulphanilic acid, and hydrochloric acid.
58. (new) The lyophilisate according to claim 56, wherein the acid of the acid addition salt is present in an amount of from 60 mg to 650 mg per 100 mg of flupirtine, preferably in an amount of 200 mg to 400 mg per 100 mg of flupirtine.
59. (new) The lyophilisate according to claim 54, further comprising at least one additive selected from the group consisting of a cake-forming agent, an antioxidant, and a detergent; wherein the cake-forming agent is preferably mannite, saccharose or glycine; wherein the antioxidant is preferably sodium bisulfate or ascorbic acid; and wherein the detergent is preferably polyvinylpyrrolidone.
60. (new) The lyophilisate according to claim 59, wherein the cake-forming agent is present in an amount of from 10 mg to 1000 mg per 100 mg of flupirtine, preferably in an amount of from 30 mg to 300 mg per 100 mg of flupirtine.

61. (new) The lyophilisate according to claim 59, wherein the antioxidant is present in an amount of from 0.5 mg to 10 mg per 100 mg of flupirtine, preferably in an amount of from 2 mg to 5 mg per 100 mg of flupirtine.

62. (new) The lyophilisate according to claim 59, wherein the detergent is present in an amount of from 10 mg to 150 mg per 100 mg of flupirtine, preferably in an amount of from 10 mg to 50 mg per 100 mg of flupirtine.

63. (new) A process for producing a flupirtine-containing pharmaceutical composition for parenteral administration, the process comprising the step of:

dissolving a flupirtine-containing lyophilisate according to claim 54 in at least one solvent, selected from the group consisting of an aqueous medium and an organic solvent, to obtain a liquid pharmaceutical composition ready for use.

64. (new) A process for producing a flupirtine-containing lyophilisate according to claim 54, the process comprising the step of:

preparing a flupirtine solution by dissolving flupirtine base in an aqueous medium;

freeze drying the flupirtine solution.

65. (new) A liquid flupirtine-containing pharmaceutical composition for parenteral administration, prepared by dissolving a flupirtine-containing lyophilisate according to claim 54.

66. (new) The pharmaceutical composition according to claim 65 in the form of a solution for injection or a solution for infusion.